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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,283	03/18/2002	Alex Cimpola	024751-00000	3629

4372 7590 07/14/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/14/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/890,283

Applicant(s)
Cimpoia et al.

Examiner
Sandra Saucier

Art Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

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DETAILED ACTION

Claims 1-16 are pending and are considered on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,541,625 [A]. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the resolution of the same substrate using some of the same enzymes, such as subtilisin, which is a protease from *Bacillus licheniformis* or lipase from *Pseudomonas cepacia* or more broadly, a proteinase (protease) from a bacteria.

Claims 1-16 are directed to an invention not patentably distinct from claims 1-19 of commonly assigned US 6,541,625 [A]. Specifically, the enzymes used are either the same or overlapping in identity. Please note that a proteinase and a protease are different names for the same enzymatic activity.

Assignee is required to either: (a) name the first inventor of conflicting subject matter under 102(f) or (g) or (b) show inventions were commonly owned

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AT TIME OF APPLICANTS' INVENTION.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1–16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Formula A is incorrect in claim 1. It should be an acid.

Claims 1 and 16 recite “an analogue or derivative thereof”. However, the metes and bounds of the claim are indefinite because it is unclear what is encompassed by this recitation, that is, how much difference may exist between the purinyl or pyrimidyl and its derivative or analogue.

Claim 1 should recite “separating the hydrolyzed compound from the compounds of the formula A or B” last line, page 70. Please consider replacing the word “product” with the “hydrolyzed compound”.

In claims 1, 10 and 13, ESL-001-02 and ESL-001-05 are uninterpretable. Is this an order number, a registered trademark, a tradename or some other definable entity? Please point to the place in the specification where the origin of this substance is disclosed.

It cannot be understood in claim 1 if the unhydrolyzed compound or the hydrolyzed compound is then further reacted with a pyridinyl/pyrimidinyl. Please revise to clearly delineate the reactions and what is being reacted to produce what.

Claims 2–5 are indefinite because the starting material cannot be the result of the hydrolyzing process, by definition. A starting material is a prereaction material. Once a reaction is run, the resultant mixture is a product. The limitation of the claim cannot be understood and is therefore, not considered in the formulation of the art rejections.

Claims 6–9 recites “the product”, however does it refer to the hydrolyzed or unhydrolyzed compound? Both of them and a mixture thereof can be said to be “products” of the reaction.

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Claims 14 and 15 should have "and" between the last two members of the Markush group.

Claim 16 cannot be understood because there are no first and second mixtures.

The claims are directed to a resolution of a mixture of α and β anomers (carbon 2) of either formula A or formula B using a hydrolytic enzyme to preferentially form an alcohol from hydrolysis of the acid group attached to carbon 4. The claim is interpreted to mean that the mixture reacted has only the two anomers, not all four stereoisomers as starting material.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
July 7, 2003

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